03-24-06

06,727,105

DAC $

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 4,650,787 Attorney Docket No. 16947-005001
Patentee : Schally et al.
Issue Date : March 17, 1987
Serial No. : 727,150
Filed : April 25, 1985
Title : BIOLOGICALLY ACTIVE OCTAPEPTIDES

Commissioner for Patents
Office of Petitions
Alexandria, VA 22313-1450

TRANSMITTAL OF APPLICATION FOR INTERIM EXTENSION OF PATENT TERM

Please find enclosed:

1. Application for Second Interim Extension of Patent Term (9 Page);
2. Exhibit A – (1 Cover page, 4 pages of Exhibit);
3. Exhibit B – (1 Cover page, 2 pages of Exhibit);
4. Exhibit C – (1 Cover page, 2 pages of Exhibit); and
5. Exhibit D – (1 Cover page, 1 pages of Exhibit).
6. Check of $220 in payment of the fee (37 C.F.R. § 1.20(j)(3).

Please apply all other charges to Deposit Account 06-1050.

Respectfully submitted,

23 March 2006

ANITA L. MEIKLEJOHN
Reg. No. 35,283

Fish & Richardson PC
225 Franklin St.
Boston MA 02110
Enclosures: Exhibits A-D

21291073.doc

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EV 664 068 639 US

March 23, 2006
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 4,650,787 Attorney Docket No. 16947-005001
Patentee : Schally et al.
Issue Date : March 17, 1987
Serial No. : 727,150
Filed : April 25, 1985
Title : BIOLOGICALLY ACTIVE OCTAPEPTIDES

MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR SECOND INTERIM EXTENSION OF PATENT TERM UNDER 35 U.S.C § 156(d)(5)

I. Pursuant to 35 U.S.C. § 156(d)(5), Debiovision Inc. ("Debiovision"), a corporation incorporated under the laws of Quebec, Canada, with its registered office at 666 Sherbrooke Street West, Suite 1400, Montreal, Quebec H3A 1E7, Canada, hereby applies for a second one-year interim extension of patent term for United States Patent No. 4,650,787 ("the '787 patent").[1] The '787 patent covers Sanvar™ Injection ("Sanvar") and methods of using Sanvar.[2] Debiovision is the current name of H3 Pharma, Inc. ("H3 Pharma"), the named applicant of the first Application for Interim Extension of Patent Term for this patent, filed April 9, 2005 ("First IE Application"). The certification of this name change ("Certificat De Modification") by Registraire des enterprise Québec on September 1, 2005 is provided as Exhibit A.

II. Debiovision certifies that it is the exclusive agent Debiopharm S.A. and Debio Recherche Pharmaceutique S.A. (collectively "Debio") for the purposes of pursuing a patent term extension for the '787 patent, by virtue of the Authorization for Debiovision to Apply for Extension of Patent Term (attached as Exhibit B) and the Authorization for H3 Pharma to Apply for Extension of Patent Term (Exhibit 2 of the First IE Application). In the Authorizations, Debio appoints Debiovision as its sole agent for the purposes of pursing interim and permanent patent term

[1] A copy of the '787 patent has been provided as Exhibit 1of the Application for Interim Extension of Patent Term for this patent, filed April 9, 2005. All exhibits identified by numbers herein refer to the exhibits filed in the Application for Interim Extension of Patent Term for this patent, filed April 9, 2005.
[2] Sanvar is also known by the trade name Octastatin™.

extensions for the '787 patent. Also, in the Authorizations, Debio certifies that Debio is the exclusive licensee of the '787 patent, by virtue of a license received from The Administrators of The Tulane Educational Fund ("Tulane"), the assignee of 100% of the right, title and interest in the '787 patent (see Exhibit 3 of the First IE Application), and that Tulane has exclusively granted all patent rights in the '787 patent to Debio, including the right to pursue patent term extensions. Debio has granted Debiovision a sublicense to the '787 patent, including the rights to develop and commercialize vapreotide acetate, the active ingredient in Sanvar.

III. Debiovision has previously provided information required by 37 C.F.R. §§ 1.740 and 1.741 in the First IE Application. Additional information is provided below with reference to the relevant part of the First IE Application:

1. The complete identification of the product currently undergoing regulatory review is Sanvar™ Injection. The active ingredient of Sanvar is vapreotide acetate, an acetate salt of vapreotide, which is a synthetic analogue of somatostatin. Vapreotide is an octapeptide having the following chemical formula:

D-Phe – Cys – Tyr – D-Trp – Lys – Val – Cys – Trp-NH_2

The line between the Cys residues indicates a disulfide linkage. The structural formula of vapreotide is shown in Exhibit 4 of the First IE Application.

Sanvar is manufactured according to the description in Drug Master File No. 17133 submitted to the Food and Drug Administration by Genzyme Pharmaceuticals on December 31, 2003. Briefly, vapreotide is synthesized by coupling peptide fragments according to the sequence indicated above, using optically pure peptides and standard segment condensation protocols, in which α-amino and α-carboxyl groups and lateral side chains are protected as necessary. The octapeptide is formed by azide coupling of the two tetrapeptide fragments (synthesized in solution). The disulphide bridge is formed by iodine oxidation. The protected octapeptide disulphide is purified by chromatography and then deprotected by treatment with formic acid. The product is purified by reverse phase HPLC chromatography and vapreotide

acetate is formed by ion exchange of vapreotide and TFA. The steps for synthesis of vapreotide acetate are outlined in Exhibit 5 of the First IE Application.

Sanvar is provided in single dose vials containing a sterile, lyophilized powder containing 0.6 mg vapreotide acetate (peptide base units) to be reconstituted to 50 mL with 0.9% Sodium Chloride Injection, USP, prior to infusion. The 0.9% Sodium Chloride Injection, USP, is not provided with Sanvar and does constitute part of the new drug application that is the basis for this application. Each vial of Sanvar contains a 10% overfill of vapreotide acetate to allow for losses during extraction and administration.

Sanvar reproduces most of the effects induced by natural somatostatin. In the pituitary gland, Sanvar inhibits the secretion of growth hormone. In the gastrointestinal tract, Sanvar inhibits the secretion of many endocrine digestive peptides, e.g., insulin, glucagon, gastrin, vasoactive intestinal peptide, secretin, and cholecystokinin. Sanvar also suppresses exocrine secretion from the pancreas and gastrointestinal tract. In the new drug application that is the basis for this application, Sanvar is indicated for the treatment of esophageal variceal hemorrhage in patients with portal hypertension.

2. Under section 505(b) of the Federal Food, Drug and Cosmetic Act, regulatory review is ongoing for new drug application (NDA) number 21-761 for Sanvar. This NDA was initially submitted on February 27, 2004 and is still under review.

3. Applicant reasonably expects that the regulatory review period for the new drug application will extend beyond the expiration of the term of the '787 patent, including the term as extended by the Certificate of Interim Extension dated October 17, 2005. An approvability letter for Sanvar was mailed on December 21, 2004 and is of record in the First IE Application as Exhibit 7.

4. Vapreotide acetate, the active ingredient in Sanvar, has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act.

5. Pursuant to 35 U.S.C § 156(d)(5)(C) and 37 C.F.R. § 1.790(a), this application is being timely submitted during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension on April 25, 2006.

6. The U.S. Patent for which an extension is being sought is United States Patent No. 4,650,787. The names of the inventors are Andrew V. Schally and Ren Z. Cai. The '787 patent was filed on April 25, 1985, issued on March 17, 1987, and will expire on April 25, 2006 pursuant to the Certificate of Interim Extension dated October 17, 2005.

7. A copy of the '787 patent is available as Exhibit 1 of the First IE Application.

8. A copy of a Maintenance Fee Statement for the '787 patent, dated February 12, 2004 is available as Exhibit 6 of the First IE Application. The Maintenance Fee Statement shows that the maintenance fees for the fourth, eighth, and twelfth years were paid on September 10, 1990, June 17, 1994, and August 17, 1998, respectively. Applicant certifies that no disclaimer, certificate of correction, or re-examination certificate related to the '787 patent has been issued.

9. As described below, claims 1, 3, 4, 6, and 14 of the '787 patent read on the product Sanvar.

Claims of '787 Patent	**How Claim Reads on Sanvar**
1. A compound of the formula A – C" – X – Z – Lys – Y – C' – B wherein A is an L, D or DL amino acid selected from the group consisting of phenylalanine (Phe), its acetylated derivatives or a pharmaceutically acceptable acid addition salt thereof; B is an L, D or DL amino acid selected from the group consisting of threonine amid (Thr NH_2), tyrosine amide (Tyr NH_2), tryptophan amide (Trp NH_2); X is L-phenylalanine (L-Phe) or L-tyrosine (L-Tyr); Y is L-valine (L-Val); Z is D-tryptophan (D-Trp); and C" and C' are L or D-cysteine (Cys), -aminobutyric acid (Abu), aspartic acid (Asp) or lysine (Lys); provided that where C' is Cys, C" is also Cys and where C' or C" are other than Cys, C" is different from C' and is other than Cys; the connecting line between C" and C' signifies a bridge selected from the group consisting of carbon/carbon, carbon/sulfur, sulfur/sulfur and amide bridges; and the pharmaceutically acceptable acid addition salts thereof.	Vapreotide, the active ingredient of Sanvar, is a compound of the formula: D-Phe – Cys – Tyr – D-Trp – Lys – Val – Cys – Trp-NH_2 wherein the line connecting the two Cys residues indicates a sulfur/sulfur bridge.
3. A compound according to claim 1 wherein C" is Cys; X is Tyr; Z is D-Trp; Y is Val; and C' is Cys.	Claim 3 reads on vapreotide, as described above with respect to claim 1.
4. A compound according to claim 1 wherein C" is Cys; X is Tyr; Y is Val; and C' is Cys.	Claim 4 reads on vapreotide, as described above with respect to claim 1.
6. A compound according to claim 1 which is – D-Phe – Cys – Tyr – D-Trp – Lys – Val – Cys – Trp-NH_2	Claim 6 reads on vapreotide, as described above with respect to claim 1.

Claims of '787 Patent	How Claim Reads on Sanvar
14. A pharmaceutical composition effective for reducing growth hormone serum levels which comprises an octapeptide of claim 1, its reduced form or a pharmaceutically acceptable acid addition salt thereof in a pharmaceutically acceptable liquid or solid carrier thereof.	Sanvar is effective for reducing growth hormone levels. Sanvar contains a sterile, lyophilized powder containing 0.6 mg vapreotide acetate, which is an octapeptide covered by claim 1, as described above. The powder is contained in a single dose vial to be reconstituted with 0.9% sodium chloride injection, USP, a pharmaceutically acceptable liquid carrier.

As described below, claim 16 of the '787 patent reads on a method of using Sanvar for the treatment of esophageal variceal hemorrhage in patients with portal hypertension, which is the indication set forth in the NDA.

Claims of '787 Patent	How Claim Reads on Method of Using Sanvar
16. A method of treating excess release of growth hormone, gastrointestinal disorders, and diabetes in a mammal in need of such therapy which comprises administering to said mammal an effective dose of octapeptide of claim 1, its reduced form, or a pharmaceutically acceptable acid addition salt thereof.	Sanvar is indicated for the treatment of esophageal variceal hemorrhage in patients with portal hypertension, which is a gastrointestinal disorder.

10. The relevant dates and information required pursuant to 35 U.S.C. § 156(g) in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

Investigational new drug (IND) application number 59,287, which covers Phase III testing of vapreotide acetate (i.e., Sanvar) for the treatment of bleeding due to pancreatic resection, was received by FDA on November 23, 1999. FDA acknowledged receipt of this application on December 1, 1999. FDA completed a Phase III protocol review for a study on bleeding during pancreatic resection on April 11, 2000. Further information is available in Exhibit 8 of the First IE Application.

New drug application (NDA) application number 21-761 for Sanvar, for the treatment of variceal hemorrhage due to portal hypertension associated with therapeutic endoscopy, was initially submitted to the Food and Drug Administration (FDA) on February 27, 2004.

A copy of the approvability letter for Sanvar is available as Exhibit 7 of the First IE Application.

11. Attached as Exhibit D is a brief description of the significant activities undertaken by Debiovision with respect to Sanvar since January 11, 2005. Activities on or prior to January 11, 2005, are described in Exhibit 8 of the First IE Application. J. Kay Noel and Associates refers to Debiovision's regulatory agent in the United States.

12. The length of the interim extension requested is one year, pursuant to 35 U.S.C. § 156(d)(5)(B), to thereby extend the term of the '787 patent to April 25, 2007. The '787 patent is eligible for the interim extension herein applied for because it satisfies all of the requirements for such interim extension as follows:

35 U.S.C. § 156(a)

The '787 patent claims the product Sanvar and a method of using Sanvar.

35 U.S.C. § 156(a)(1)

The term of the '787 patent has not expired before submission of this application.

35 U.S.C. § 156(a)(2)

The term of the '787 patent has never been extended under 35 U.S.C. § 156(e)(1).

35 U.S.C. § 156(a)(3)

The application for interim extension is submitted by Debiovision, as the agent of Debio, which is the agent of Tulane, the owner of record, as discussed above.

35 U.S.C. § 156(a)(4)

The product, Sanvar, is subject to a regulatory review period before it can be commercially marketed or used.

35 U.S.C. § 156(a)(5)(A)

The commercial marketing of the product, Sanvar, after the regulatory review period indicated herein, will be the first permitted commercial marketing of the product under section 505(b) of the Federal Food, Drug and Cosmetic Act, under which such regulatory review is occurring.

13. Debiovision acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought by this application.

IV. By the power of attorney attached as Exhibit C, Debiovision appoints Anita L. Meiklejohn, Ph.D., Reg. No. 35,283, and Ramon K. Tabtiang, Reg. No. 55,658, of Fish & Richardson P.C., as its attorneys to prosecute its application(s) for patent term extension of U.S. Patent No. 4,650,787 and to transact all business in the Patent and Trademark Office connected therewith with full powers of substitution and revocation.

V. Please direct all communications regarding the application to

ANITA L. MEIKLEJOHN
FISH & RICHARDSON P.C.
225 Franklin St.
Boston MA 02110
Telephone: (617) 521-7041
Facsimile: (617) 542-8906

This correspondence address updates and supersedes the address provided in the Power of Attorney.

VII. The application is accompanied by two additional copies of the application.

VII. It is respectfully requested that this Application for a Second Interim Extension of Patent Term Under 35 U.S.C. § 156(d)(5) and 37 C.F.R. § 1.790 of United States Patent No. 4,650,787 be granted.

VIII. The prescribed fee of $220.00 for receiving and acting upon the application for subsequent extension, pursuant to 37 C.F.R. § 1.20(j)(3), is enclosed. Please apply all other charges or credits to Deposit Account 06-1050.

Respectfully submitted,

23 March 2006

ANITA L. MEIKLEJOHN
Reg. No. 35,283

Fish & Richardson PC
225 Franklin St.
Boston MA 02110
Enclosures: Exhibits 1-6

21288359.doc

EXHIBIT A

"Certificat De Modification" by Registraire des enterprise Québec

(including translation)

Québec

CERTIFICAT DE MODIFICATION

Loi sur les compagnies, Partie IA
(L.R.Q., chap. C-38)

J'atteste par les présentes que la compagnie

DEBIOVISION INC.

a modifié ses statuts le ***1ER SEPTEMBRE 2005,*** en vertu de la partie IA de la Loi sur les compagnies, comme indiqué dans les statuts de modification ci-joints.

Déposé au registre le 1er septembre 2005
sous le matricule 1149653793

Registraire des entreprises Québec

Registraire des entreprises par intérim

E130Z13I97D30SA

Registraire des entreprises
Québec

Statuts de modification

Loi sur les compagnies (L.R.Q., c. C-38, partie IA)

1. Nom - Inscrire le nouveau nom de la compagnie si celui-ci est modifié et inscrire le nom antérieur à la section 5.
ou
- Inscrire le nom actuel si vous le conservez et inscrire S. O. à la section 5.

Numéro d'entreprise du Québec (NEQ): 1 1 4 9 6 5 3 7 9 3

DEBIOVISION INC.

Marquer la case d'un X si vous demandez un numéro matricule (compagnie à numéro) au lieu d'un nom. ☐

2. Les statuts de la compagnie sont modifiés de la façon suivante :

BEST AVAILABLE COPY

3. Date d'entrée en vigueur (si différente de la date du dépôt des statuts de modification) pour les demandes qui ne sont pas visées par la section 4.

Date postérieure à celle du dépôt : Année ____ Mois ____ Jour ____

4. Modification des statuts en vertu de l'article 123.140 et suivants de la *Loi sur les compagnies*

Marquer la case d'un X si la demande de modification est présentée pour rectifier une illégalité, une irrégularité ou pour y insérer une disposition requise par la *Loi sur les compagnies* :
- qui ne porte pas atteinte aux droits des actionnaires ou des créanciers (art. 123.140); ☐
- qui peut porter atteinte aux droits des actionnaires ou des créanciers - joindre copie du jugement (art. 123.141). ☐

Date d'entrée en vigueur (la modification rétroagit à la date du certificat accompagnant les statuts que l'on modifie, à moins que les présents statuts ou le jugement ne mentionnent une date ultérieure) : Année ____ Mois ____ Jour ____

5. Nom antérieur à la modification (si différent de celui mentionné à la section 1).

H3 PHARMA INC.

Québec
Déposé le
1er SEP. 2005
Le registraire des entreprises

Signature de l'administrateur autorisé

Si l'espace prévu est insuffisant, joindre une annexe remplie en deux exemplaires, identifier la section correspondante et numéroter les pages s'il y a lieu.

SIGNER ET RETOURNER LES DEUX EXEMPLAIRES AVEC VOTRE PAIEMENT.
NE PAS TÉLÉCOPIER.

Québec

Certificate of Amendment

CERTIFICAT DE MODIFICATION

Companies Act, Part IA

Loi sur les compagnies, Partie IA
(L.R.Q., chap. C-38)

I attest by the following that the Company

DEBIOVISION INC.

has amended its articles on September 1, 2005 according to Part IA of the Companies Act as indicated in the attached Articles of Amendment.

J'atteste par les présentes que la compagnie

DEBIOVISION INC.

a modifié ses statuts le ***1ER SEPTEMBRE 2005***, en vertu de la partie IA de la Loi sur les compagnies, comme indiqué dans les statuts de modification ci-joints.

BEST AVAILABLE COPY

Entered in the register on Sept. 1,2005 under its business # 1149653793

Registraire des entreprises Québec

E130Z13I97D30SA

Déposé au registre le 1er septembre 2005 sous le matricule 1149653793

The Enterprise Registrar

Registraire des entreprises par intérim

Translated by:

Lydia Hetenyi - H3 Pharma Inc.

Enterprise Registrar

Articles of Amendment

Registraire des entreprises Québec

Statuts de modification

Loi sur les compagnies (L.R.Q., c. C-38, partie IA)

Name: write the new name of the company if this one has been modified and write the previous name at section #5 OR write the actual name if you retain it and write n/a at Section 5

1. Nom - Inscrire le nouveau nom de la compagnie si celui-ci est modifié et inscrire le nom antérieur à la section 5.
ou
- Inscrire le nom actuel si vous le conservez et inscrire S. O. à la section 5.

Numéro d'entreprise du Québec (NEQ): 1 1 4 9 6 5 3 7 9 3

Companies Act, Part IA Business # NEQ114965-3793

DERTOVISION INC.

(write X in the box if you request a business # instead of a name)
Marquer la case d'un X si vous demandez un numéro matricule (compagnie à numéro) au lieu d'un nom. ☐

2) Company Articles have been amended as follows:

2. Les statuts de la compagnie sont modifiés de la façon suivante :

BEST AVAILABLE COPY

3) Effective date (if different than date of entry)

3. Date d'entrée en vigueur (si différente de la date du dépôt des statuts de modification) pour les demandes qui ne sont pas visées par la section 4.

Date postérieure à celle du dépôt : Année Mois Jour

4. Modification des statuts en vertu de l'article 123.140 et suivants de la *Loi sur les compagnies*

Marquer la case d'un X si la demande de modification est présentée pour rectifier une illégalité, une irrégularité ou pour y insérer une disposition requise par la *Loi sur les compagnies* :
- qui ne porte pas atteinte aux droits des actionnaires ou des créanciers (art. 123.140); ☐
- qui peut porter atteinte aux droits des actionnaires ou des créanciers - joindre copie du jugement (art. 123.141). ☐

Date d'entrée en vigueur (la modification rétroagit à la date du certificat accompagnant les statuts que l'on modifie, à moins que les présents statuts ou le jugement ne mentionnent une date ultérieure) : Année Mois Jour

4) Amendment of Articles as per Sect. 123.140 and following the Companies Act.

5) Name prior to amendment (if different than that mentioned in Section 1)

5. Nom antérieur à la modification (si différent de celui mentionné à la section 1).

H3 PHARMA INC.

Québec Déposé le 1 SEP 2005 Le registraire des entreprises

Entered on Sept. 1, 2005 Enterprise Registrar

Signature de l'administrateur autorisé

Si l'espace prévu est insuffisant, joindre une annexe remplie en deux exemplaires, identifier la section correspondante et numéroter les pages s'il y a lieu.

Signature of authorized Director

01104-1 (2004-10) E

SIGNER ET RETOURNER LES DEUX EXEMPLAIRES AVEC VOTRE PAIEMENT.
NE PAS TÉLÉCOPIER.

Sign and return both originals with your payment. Do not telefax.

Translated by:

Lydia Hetenyi - H3 Pharma Inc.

If space provided is insufficient, attach an annex, in duplicate, identify the corresponding Section and number of pages, if applicable

EXHIBIT B

Authorization for Debiovision to Apply for Extension of Patent Term

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 4,650,787
Patentee : Schally et al.
Issue Date : March 17, 1987
Serial No. : 727,150
Filed : April 25, 1985
Title : BIOLOGICALLY ACTIVE OCTAPEPTIDES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AUTHORIZATION FOR DEBIOVISION INC.

TO APPLY FOR EXTENSION OF PATENT TERM

Pursuant to 37 C.F.R. § 1.730, Debiopharm S.A. and Debio Recherche Pharmaceutique S.A. (collectively "Debio") hereby appoint Debiovision Inc. ("Debiovision"), a Canadian corporation, as Debio's sole agent for the purposes of pursuing interim and permanent patent term extensions for United States Patent No. 4,650,787 ("the '787 patent"), as provided under 35 U.S.C. § 156. Debiovision Inc. is the current name of H3 Pharma, Inc., the agent identified in the Authorization for H3 Pharma to Apply for Extension of Patent Term signed March 16, 2005 and submitted to the United States Patent and Trademark Office as Exhibit 2 of the Application for Interim Extension of Patent Term of April 9, 2005.

Debiovision will do all things useful or necessary in order to seek and obtain such patent term extensions for the '787 patent. Debio will provide Debiovision with all information requested by Debiovision for purposes of pursuing such patent term extensions for the '787 patent.

Debio certifies that The Tulane Educational Fund ("Tulane") is the assignee of 100% of the right, title and interest in the '787 patent by virtue of an Assignment from Andrew V. Schally and Renzhi Z. Cai, to Tulane, recorded in the Patent and Trademark Office on June 15, 1987 at reel 4726, frame 0891, a copy of which is attached. Debio certifies that Debio has authority to seek a patent term extension for the '787 patent by virtue of Tulane having granted Debio an exclusive, worldwide, irrevocable, and fully paid up license to the '787 patent, including the unfettered right to grant sublicenses, or pledge or assign Debio's rights under the license. Debio has granted Debiovision a sublicense to the '787 patent, including the rights to develop and

commercialize vapreotide, including vapreotide acetate. The undersigned has reviewed the documents referred to herein, and to the best of the undersigned's knowledge and belief, title is in Tulane and Tulane has exclusively granted all patent rights in the '787 patent to Debio, including the right to pursue patent term extensions.

The undersigned, whose title is supplied below, is empowered to act on behalf of Debio.

The undersigned hereby declares that all statements made herein of the undersigned's own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted

Date: March 22, 2006

Name: Rolland-Yves Mauvernay
Title: President and C.E.O of
Debiopharm S.A.
and of
Debio Recherche Pharmaceutique S.A.

EXHIBIT C

Power of Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 4,650,787
Patentee : Schally et al.
Issue Date : March 17, 1987
Serial No. : 727,150
Filed : April 25, 1985
Title : BIOLOGICALLY ACTIVE OCTAPEPTIDES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

POWER OF ATTORNEY

Pursuant to 37 C.F.R. § 1.730, Debiovision Inc. ("Debiovision"), hereby appoints Anita L. Meiklejohn, Ph.D., Reg. No. 35,283, and Ramon K. Tabtiang, Ph.D., Reg. No. 55,658, both of Fish & Richardson P.C., as its attorneys to prosecute its application(s) for patent term extension of U.S. Patent No. 4,650,787 and to transact all business in the Patent and Trademark Office connected therewith with full powers of substitution and revocation.

1. The undersigned, an authorized representative of Debiovision, verifies that H3 Pharma Inc. changed its name to Debiovision Inc, pursuant to a certification ("Certificat De Modification") by Registraire des enterprise Québec on September 1, 2005 (filed herewith). H3 Pharma Inc. was the named applicant of the Application for Interim Extension of Patent Term for the '787 patent, filed April 9, 2005.

2. The undersigned, an authorized representative of Debiovision, verifies that Debiovision is the exclusive agent Debiopharm S.A. and Debio Recherche Pharmaceutique S.A. (collectively "Debio") for the purposes of pursuing a patent term extension for the '787 patent, by virtue of the Authorization for Debiovision to Apply for Extension of Patent Term ("Authorization"). In the Authorization, Debio certifies that: (i) The Tulane Educational Fund ("Tulane") is the assignee of 100% of the right, title and interest in the '787 patent by virtue of an Assignment from Andrew V. Schally and Renzhi Z. Cai, to Tulane, recorded in the Patent and Trademark Office on June 15, 1987 at reel 4726, frame 0891; and (ii) Debio has authority to seek a patent term extension for the '787 patent by virtue of Tulane having granted Debio an exclusive, worldwide, irrevocable, and fully paid up license to the '787 patent, including the unfettered right to grant sublicenses, or pledge or assign Debio's rights under the license. Debio

has granted Debiovision a sublicense to the '787 patent, including the rights to develop and commercialize vapreotide acetate, the active ingredient of Sanvar. Debio has is also the sole owner of Debiovision.

Please direct all communications regarding the application to

ANITA L. MEIKLEJOHN
FISH & RICHARDSON P.C.
225 Franklin St.
Boston MA 02110
Telephone: (617) 521-7041
Facsimile: (617) 542-8906

Respectfully submitted,

DEBIOVISION INC.

Signature: _____ Date: March 22, 2006

Name: Loic Maurel

Title: President & C.E.O.

DEBIOVISION INC.